

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy and Marine Corps Research

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Comment

Extramurals: A Decisive Role in Research

Earlier this year the DON HRPP noted the award of the 300th DoD-Navy Addendum to the Federalwide Assurance, or FWA, since the Addendum became a requirement for non-DoD institutions that seek Department of the Navy funding for research with human subjects.

Research conducted by colleges and universities, contractors, and other private organizations in a vast range of disciplines long has played a critical role in the development of Fleet/Force operational capabilities.

Rear Adm. Bruce Doll, in remarks in an interview for this issue (page 8), says that universities “have very talented personnel and skills, which serve as a resource for us,” adding that the extramurals make a long-term commitment to retain those kinds of capabilities.

Active-duty Navy personnel, he says, can’t make such commitments because they rotate continuously to new assignments.

Patti Yasenchak, DON HRPP’s Extramural Research Coordinator, puts it succinctly: “The Navy depends on extramural performers.”

The Navy’s extramural research performers include the largest and most prominent universities and research organizations in the U.S., as well as smaller, less-well known institutions and highly specialized

laboratories. For example, MIT has conducted systematic analyses of the interaction of human and robot teams. The University of California Los Angeles has developed interactive game-based technologies to enhance understanding of problem-solving, and The Johns Hopkins Bloomberg School of Public Health has studied vaccine development.

Meanwhile, Gettysburg College researchers have collaborated with others at the U.S. Naval Academy for original studies of experimental economies. Adaptive Technologies Inc. has worked on improving custom hearing-protection gear.

Addendum holders include Stanford University, Vanderbilt, Northwestern, Penn State, Harvard Medical School, Batelle Labs, Carnegie Mellon, SAIC, Worcester Polytech, and General Dynamics.

Others are SRI International, the Brain Trauma Foundation, Sandia National Laboratories, Anthrotronix Inc., and Mount Aloysius College.

These institutions complete the Addendum, which highlights unique standards not required for non-Navy work. To obtain an approved Addendum the institutions must validate the qualifications of their research staffs, which go through demanding HRPP training.

The DON HRPP has streamlined the Addendum process decisively. Applications now are approved by the Director, rather than going through a chop chain to the Navy Surgeon General.

The payoff for the Navy is a flow of genuine breakthroughs in many critical fields aimed at enhancing the safety, health, and operational capabilities of Navy and Marine Corps personnel.

DON HRPP is still working to improve the process, helping the Sea Services to benefit from the ingenuity and creativity of dedicated researchers at work throughout the extramural community.

Also in this Issue

CAPT Keith Lehnhardt, NEDU CO, discusses supporting Navy undersea operations

ONR’s Steele, D’Angelo on Undersea Medicine, National Naval Responsibility

RADM Bruce Doll (Part II): “Preserving HRPP Capability”

Navigating CITI Online: Picking Tracks and Learner Groups

*Director's Notes***NEDU, NSMRL: “Partnering with Warfighters”***By CAPT Alan F. Nordholm*

This issue features a fascinating interview with CAPT Keith Lehnhardt, Commanding Officer, Navy Experimental Diving Unit and an accompanying article on the Undersea Medicine program managed at the Office of Naval Research. Both pieces highlight the broad scope of the Navy's work across the undersea mission domain.

As CAPT Lehnhardt says in his initial comments, “NEDU partners with the warfighter.” He cites many examples of how the Command does so: studies of methodologies for alleviating hypoxia and the effects of pressure, oxygen, and other factors on divers, among many others. He describes NEDU's work for the fleet and for the Army and Marine Corps. Because pilots of high-performance aircraft experience some of the same phenomena as divers, NEDU also supports critical Air Force research.

Similarly, the Naval Submarine Medical Research Lab in Groton, Conn., explores the complex

components of submariners' health, such as vitamin D deficiency, bone health, disrupted sleep, and others. NSMRL and other Navy labs are evaluating the impact of deploying women aboard submarines. NSMRL also is looking at the potentially traumatic effects on the human body of underwater sound, which are unavoidable as divers carry out repairs and routine maintenance. Such studies provide the baseline for development of new equipment and protective systems for divers.

Some of this research involves the use of human subjects. In any event, the scope, and oftentimes the risk involved in the tough and dangerous work at NEDU and NSMRL, and the efforts of the incredibly talented physicians, engineers, divers, and support personnel who do it, remind us of the non-negotiable importance of DON HRPP's work: protecting our fellow Navymen and women, as they carry out this research in support of diving and undersea missions.

*Education and Training***Navigating CITI DON HRPP Online Training**

For HRPP staffers seeking to complete required training through the CITI website, navigating the site may pose a dilemma: selecting the right track, either biomedical (BIO) or social behavioral (SBR), and then choosing the appropriate learner group in order to complete the required training.

Staffers sometimes believe, incorrectly, that they must complete both the BIO and SBR tracks for the same learner group. In developing the two tracks, DON HRPP was careful to include comprehensive information on both because the two disciplines often overlap in the BIO area. BIO components are relatively rare in SBR research, so the SBR track does not convey BIO information. One should select BIO if engaged in both.

Another potential source of confusion is selecting the right learner group (among 12 to choose

DON HRPP Director CAPT Alan Nordholm has signed new Training & Education Guidance, which incorporates DoD's Minimum Education Requirements issued last year. Commands will receive an E-Gram advising how to implement the new guidance.

from), especially if an individual has more than one role in research. For individuals serving in multiple roles, coursework must be completed that is most comprehensive. For example, vaccine research and diving research study the body's response to physical stimuli and have a biomedical focus, whereas human factors and human cognition research tend to emphasize social-behavioral

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Command Interview

NEDU's Keith Lehnhardt: "Diving Is Our Bread and Butter"

Interview with CAPT Keith Lehnhardt, Commanding Officer, Navy Experimental Diving Unit (Panama City, Fla.)

CAPT Lehnhardt assumed command at NEDU in 2011. A native of Decatur, Ill., CAPT Lehnhardt earned his B.S. in oceanography at the U.S. Naval Academy in 1991. Upon completion of the nuclear pipeline, he served as a division officer aboard the attack submarine Norfolk (SSN-714) until 1996. He then earned his M.S. in mechanical engineering and a Naval Engineer's degree at MIT. Assigned to the Portsmouth Naval Shipyard in 2000, he conducted overhaul and repair activities on Providence (SSN-719) and Miami (SSN-755) and served as Command Diving Officer and project engineer for the Advanced Seal Delivery System and the Atmospheric Diving System. He joined the Deep Submergence Unit in 2007 as officer-in-charge of the Diving Systems Detachment. In 2007 CAPT Lehnhardt reported to NAVSEA's Advanced Undersea Systems directorate as Assistant Program Manager for Special Systems Acquisition. He is qualified in submarines, deep submergence systems, and as a deep sea diver and salvage officer.

Please provide some insight on NEDU's mission.

NEDU partners with the warfighter. We develop timely and cost-effective solutions to support operations in undersea and other extreme environments. We do this through biomedical research and through independent testing and evaluation of equipment and procedures.

Diving is our bread and butter—undersea-type environments—but we also work in other extreme environments associated with chem/bio, mine safety, aviation, and space systems.

So your charter is much broader than supporting the Naval Sea Systems Command.

Our primary role is to support NAVSEA and Navy tasking, but because the Department of the Navy supports diving throughout all of the DoD, we

regularly do testing for Army, Marine Corps, Air Force and Special Forces diving systems as well.

Our scientists, engineers and researchers have expertise in a wide range of areas, so, if there's time, we'll take on non-diving related work that other organizations may have for us, such as the Air Force or NIOSH [National Institute for Occupational Safety and Health]. We've even done work for NASA in the past related to their Extra Vehicular Activity (EVA) or "spacewalk" programs.



Lehnhardt, wearing a "dry suit," prepares for a test dive

Similarities between space-walking and diving?

Yes, when an astronaut undertakes an EVA, their body is exposed to a lower-pressure environment and there's a strict oxygen pre-breathing regimen that must be followed to avoid altitude decompression sickness—it's almost like coming up to the surface following a shallow saturation dive. NEDU's experts have helped to integrate manned test data into models that specify the pre-breathing requirements for these astronauts.

What work do you do for NIOSH?

Currently, our NIOSH work is associated with mine safety—testing mine escape and mine rescue devices and providing feedback for methods of

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“Projects Get Funded Because of an Operational Need”

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improvement. This is ongoing work that falls into our “test and evaluation of equipment and procedures” area rather than the biomedical side.

I was not aware of the work with aviators ...

Right now, we have a couple of studies underway related to aviation. We are conducting Navy-sponsored research associated with the incidence of hypoxia under various altitude conditions. Also, we’re working with the Air Force on potential improvements to some of their aircraft breathing

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NEDU’s Ocean Simulation Facility, with a 55,000- gallon capacity, can simulate depths of 2,250 feet. Shown here: the OSF is readied for testing the SEAL delivery vehicle.

systems. And when you think about it, all these extreme environments, whether for chem-bio, mine safety, diving, or aviation, involve the same basic principles of physiology—you have to be able to breathe oxygen in all those environments and get rid of carbon dioxide. So the same principles apply whether you’re diving a Mk 25 UBA [underwater breathing apparatus] in the water, or breathing off the F-22 [Raptor fighter aircraft] breathing system at altitude. It still matters that you get oxygen to the person who needs it, and that they don’t wear themselves out breathing off of the system that supplies the oxygen.

NEDU is one of the Navy’s preeminent labs for the undersea medicine program ...

Yes. We have a diverse staff of people who specialize in underwater physiology, which looks at the effects of pressure, oxygen, carbon dioxide,

other inert gases, and water temperature on the human body, and how to best mitigate the physiological factors, so that the Navy can safely and efficiently conduct its diving missions—special warfare, ship’s husbandry, and salvage diving.

Is your focus on tactics and procedures, or on specific equipment, or both?

We focus on procedures and equipment testing and leave the tactics to the warfighter. If the operators want to utilize currently existing equipment, but in a new way that is not covered in the U.S. Navy Diving Manual, we help them develop safe procedures to meet their needs. Likewise, if new equipment is needed for a specific mission, we will conduct testing to set the bounds for safe operational employment.

NEDU conducts advanced scientific research ...

Yes, we receive funding from organizations like ONR and NAVSEA specifically dedicated to human physiology testing. We are conducting testing to determine human performance and pulmonary oxygen toxicity guidance for repeated six-hour resting and exercise dives.

We also have an ongoing study to provide pulmonary oxygen toxicity guidance for exposures beyond oxygen partial pressures of 1.3 atmospheres. Additionally, we are about to start manned testing to investigate the effects of carbon dioxide on exercise endurance and cognition while breathing from a UBA.

I would like to stress that these research projects get funded because of an operational need. For example, the “human performance and pulmonary oxygen toxicity guidance for repeated six-hour resting and exercise dives” study that’s going on right now was undertaken in response to reports from the Naval Special Warfare community of excessive fatigue and exercise intolerance following repeated, long-duration dives using high partial pressures of oxygen in their breathing mix.

It is always important to tie the research to a direct operational need so that we can better support the warfighter.

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“... A Broad Base of Scientific, Engineering, and Operational Expertise”

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What are some other research directions?

We also do a lot of testing with heated garments and research associated with the calorimetry of the human body—the body’s heat balance, so to speak.

If there is a limited amount of power available to heat a diver, how do you use that power most effectively to keep him (or her) warm during long underwater missions in low water temperatures?

NEDU is working to answer that

question. Another area of cutting-edge research that is unique to NEDU takes place in our whole-cell, hyperbaric, electrophysiology lab. By exploring the effects that various breathing gas mixes containing nitrogen and helium have on cells in a pressurized



Gear testing, submerged USN

environment, our researchers hope to better understand the mechanisms that cause nitrogen narcosis and high-pressure nervous syndrome and possibly, in the future, minimize these conditions.

What trends do you see for the future of diving?

In the past few years, our work has focused on developing procedures and testing diving-related equipment used to support longer-duration underwater missions utilizing re-breather type, self-contained underwater breathing apparatuses. There’s a lot more change in this area than in hard-hat diving. People want to stay in the water longer and not be encumbered with bulky or tethered equipment.

Self-contained—meaning SCUBA-type tanks?

Self-contained—yes, but not necessarily the SCUBA equipment traditionally used in recreational diving. Re-breather-type UBAs

capture the diver’s exhaled breathing gas, remove carbon dioxide byproducts and replenish the breathing medium with oxygen before it is inhaled again by the diver. These types of closed-circuit diving apparatuses provide distinct advantages when compared to traditional open-circuit SCUBA—more efficient use of breathing gas, longer diving durations, less noise in the water, no bubbles on the surface, etc.

Does NEDU team with other labs or universities?

We have partnered with the Naval Submarine Medical Research Laboratory and with Duke University and SUNY-Buffalo.

The best example of partnering is our relationship with the Naval Surface Warfare Center’s Panama City Division right next door. They are the center of excellence for the engineering and support of diving equipment, and a lot of the stuff that they develop we get here for testing. It’s very convenient to get the people who do the testing and evaluation in the same room as the engineers who make the equipment.

What’s the makeup of the NEDU team?

People are our most important asset. We have a very diverse organization in the sense of our skill sets, composed of both civilian and military personnel. We have 99 military billets and 41 DoD civilian positions. In addition, we have seven contracted staff members and four research personnel from Duke and SUNY Buffalo.

NEDU provides a very broad base of scientific, engineering and operational expertise—numerous Ph.D.s and M.D.s specializing in exercise physiology, experimental psychology, cellular physiology, chemistry, decompression modeling, undersea hyperbaric medicine, biophysics and much more. We also have computer, ocean, mechanical and electrical engineers working side by side with fleet operators—divers and diving supervisors.

By putting this vast spectrum of talent and expertise together, or at least a subset of it, we can take on any problem that a customer has, look at it from many different angles and give them the best product possible.

Undersea Medicine: A National Naval Responsibility

The Office of Naval Research's National Naval Responsibilities (NNR) initiative seeks S&T answers to support the Navy's most critical operational priorities. In collaboration with the Navy and DoD research community, ONR is developing technologies that enhance capability in the five NNRs: Ocean Acoustics, Undersea Weapons, Naval Engineering, Sea-based Aviation, and Undersea Medicine.

Dr. Bill D'Angelo and LCDR Chris Steele are the program officers for ONR's Warfighter Performance Department responsible for executing ONR's efforts supporting the Undersea Medicine NNR. Steele says that "It's of national importance to better understand the undersea environment, as our [Naval] military needs arise, and to act as good stewards of the sea," he says.

Undersea Medicine, he says, addresses not only health-related problems that occur in diving with the dangers of decompression sickness ("the bends"), nitrogen narcosis, and the use of hyperbaric oxygen therapy, among others, but also protecting the health and optimizing the performance of submarine crews. The ONR Undersea Medicine program works closely with scientists and engineers in academia, industry, and government laboratories.

D'Angelo points out that "the focus is on the Navy diver in the rescue, repair, salvage, special warfare, and explosive ordnance disposal communities." The Undersea Medicine program also teams with the Naval Submarine Medical Research Laboratory (NSMRL) in support of the submarine force. NSMRL pursues many initiatives focused on underwater bioeffects. For example, the lab is conducting research on the effects of underwater sound on divers. "Sound energy transmits more efficiently through water than through air, so human beings can be exposed to levels of sound in the water that are potentially more harmful than they would be in air," Steele says.

Acoustic energy transmitted through water passes through the human body, until it hits the body's cavities—sinuses and lungs, which are vulnerable

to injury caused by sound underwater. This is a concern, Steele says, because divers use tools that generate noise, for example, in removing paint and barnacles, making repairs, and other ship husbandry tasks. The tools themselves and the diving equipment generate noise; even the bubbles caused by the diver's breathing are a source of significant noise. ONR's Noise-Induced Hearing Loss program, managed by Dr. Kurt Yankaskas, is studying ways of reducing the noise exposure of divers.

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Navy divers returning from training/maintenance dive

In a separate study, NSMRL is looking at the vitamin D levels and bone health of submarine crews to determine if the lengthy deployments aboard submarines, and the resulting vitamin D insufficiency, affects bone health over time.

Steele says that "human beings experience a seasonal drop in vitamin D levels in the winter months," due to the declination of the sun, when you don't get active vitamin D conversion in your skin.

"We do know that submariners' vitamin D levels drop. NSMRL has collected data from SSBN [nuclear-powered ballistic-missile submarine] crews, which go to sea for six months or so and for the most part, stay submerged, so you get pre- and post-deployment measurements of bone health."

The study aims to better understand and more effectively characterize the undersea environment.

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“We Continue to Offer Guidance and Find New Directions ...”

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NSMRL also is studying the sleep/wake cycles of submariners, which are disrupted by the stressful cycles of watchstanding, to determine how they affect health and performance.

“We know that circadian rhythms are not maintained from a light and dark perspective in many of our operational environments in the military. The key is that man is used to daily rhythms,” he says, explaining that the operational demands aboard a submarine are such that watch schedules don’t allow time for crew members to routinely get six or seven hours of sleep per night. Schedules on many boats, he says, are based on changing shifts every 18 hours, resulting in reduced or fragmented sleep of crews.

The real challenge is providing the most optimal scheduling that accommodates performance and health of the crew while allowing flexibility to handle operational challenges.

Typically, the sleep studies are based on the submarine’s schedule, but also may be based on crew section levels or even those of individual crew members. Steele points out that if a boat is going through a heavy schedule of training drills or maintenance, the crew may not be getting consistent sleep, regardless of the watch schedule. This sleep deficiency, he says, might degrade the individual crew member’s ability to perform.

One possible solution might be to provide more learning stimuli, perhaps by improving the lighting aboard submarines.

NSMRL also has carried out important studies of the impact of the introduction of women aboard submarines. In late 2011, 17 female officers began orientation for integration aboard Navy submarines. In December 2012, three female officers, all U.S. Naval Academy graduates, received their submariner’s dolphin insignia after a year of deployed service, one completing a tour aboard *Wyoming* (SSBN-742) and two aboard *Maine* (SSBN-741).

Steele says that NSMRL, along with ONR “played a critical role” in studying the health and dietary

concerns and psychological aspects of introducing women into the small, insular submarine community. Because calcium management in females has been a historical concern, he adds, the women-aboard subs study provided impetus to NSMRL’s vitamin D and bone health study.

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Rear Adm. James Caldwell, Commander, Submarine Force, U.S. Pacific Fleet, congratulates Lt. j.g. Amber Cowan, assigned to USS Maine, for earning her submarine warfare officer device. Cowan is one of the first female unrestricted line officers to qualify in submarines.

“Integrating new personnel into a tightly knit group is a delicate challenge,” Steele says. Women assigned to submarines also lack mentors, because there are no senior female submariners. That’s a leadership challenge, but also involves sociology, psychology, and physiology.”

He adds that the NSMRL’s current study of women on subs, as well as other individual investigations in Undersea Medicine may come and go with funding cycle—science in these areas will continue.

“In the same way that the roles of the submarine force and the diving community persist, science and our National Naval Responsibility in Undersea Medicine continues to offer guidance and find new directions,” Steele says.

“We have a long-term investment in leading S&T efforts to assist with improvements in performance, health, training and education of our force.”

Leadership Interview Part II of II**Doll: “Preserving Our Capability to Enhance Performance and Readiness”**

Rear Adm. Bruce A. Doll is Commander, Naval Medical Research and Development Command/ Special Assistant to the Chief, Bureau of Medicine and Surgery for Research Protections and Director, Office of Research Protections. A graduate of Colgate University, he was awarded his Navy Reserve commission in 1981. He earned his Doctor of Dental Surgery degree at the State University of New York at Buffalo School of Dentistry. In his first Navy assignment he served as an assistant dental officer at the Naval Branch Dental Clinic, China Lake, Calif., and then as officer-in-charge, 1st Battalion Service Support Group. From 1985 to



1987 he served as dental department head aboard USS Juneau (LPD 10). Admiral Doll served as Periodontics department head and training officer at the U. S. Naval Academy dental clinic. Later, he served as commanding officer, NR OHSU National Naval Medical Center. He

deployed as commanding officer, Navy Expeditionary Medical Unit, for Operations Enduring Freedom and Iraqi Freedom. Upon his return he served as deputy commander, Navy Medicine East and deputy chief, Navy Reserve Dental Corps. Admiral Doll also served as chief operating officer for the Rutgers University/Cleveland Clinic research consortium focusing on regenerative medicine for the Wounded Warrior. Prior to his current assignment, he was medical advisor at NATO, ACT and Command Surgeon for U.S. Joint Forces Command.

The Navy’s medical Commands long have protected human subjects, but the non-medical community—the Systems Commands, operating forces, and training commands—are still getting used to it. What’s the right tactic for both sides?

We constantly have new individuals coming into these communities who are very motivated to serve. It’s our responsibility to educate them. There are training courses, and the site visits, which are inspections, but more importantly are meant to educate people on how they can be compliant, or how a facility can support those sailing directions I mentioned [see Part 1, Winter **RPU**] or, within our own Navy medical community, the SG’s interest in readiness, force health protection, and the global health initiatives.

There are many talented and motivated people who want to ask these questions. We have representatives well-versed in this at all our Medical Treatment Facilities. They’re also well-versed in the administrative oversight conducted by Institutional Review Boards (IRBs).

Is that true also of the SYSCOMs?

At some of the acquisition Systems Commands, the IRB may not be as visible because of the structure of the Command. But just because the Systems Commands and other non-medical Commands are not traditionally clinical settings for human research, they are not exempt from requirements for compliance if humans are involved. That awareness tends to reduce the number of accidents and poorly conceived projects.

What about extramural research?

We’re allied with various universities for many initiatives, for example, transplant medicine, various orthopedic therapies, and prosthetics. The universities have very talented personnel and skills, which serve as a resource for us; there’s usually a long-term commitment by the university to retain those capabilities, while we tend to rotate every three or four years.

While universities have their IRBs, they have to comply with the DoDI and the SECNAVINST, and there are specific citations to ensure they are compliant. I am aware of about 21 of these within the DoD and SECNAV instructions that look at the

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Doll: “Enhancing Performance and Readiness”

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requirements in an extramural relationship that must be met prior to starting the project.

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The littoral combat ship Freedom (LCS-1) arrives at Joint Base Pearl Harbor-Hickam in early March.

Can you offer some perspective on the potential impact on human research protections of the standup of a Defense Health System?

As long as these cost efficiencies translate to outcomes that are of benefit to one or more of the Services, it is an attractive prospect. The connectivity comes from shared capabilities in this environment, where we will confront fiscal constraints. We can address those constraints with appropriately integrated projects and at the same time preserve our capability to enhance areas of performance and readiness that are key to any particular Service.

You have potential, subtle differences in how each Service interprets the DoDI. But I think that is certainly surmountable. I would say that there are

two aspects of the mission that these projects may impact: how important the project is to a particular Service, and how closely tied it is to that Service's mission. We conceive of human research projects that impact global health in terms of readiness and force health protection, because we know that these ultimately feed into the CNO's sailing direction.

While there may be subtle differences in Service doctrine for research protections, they have not impeded approaches to how human performance can be enhanced.

So I see harmonization as favorable to the extent that it enhances the Services' missions. Those missions to some degree are defined by what we are doing today in theater, and by our future obligations.

With the CNO's emphasis on a 60-40 distribution of our Navy assets, Pacific versus Atlantic, we will be operating over a huge surface area. When an individual near the point of engagement is hurt, the time needed to transport him back could be significantly impacted by the proximity of host/friendly nation capabilities or a hospital ship. What does a first responder require in order to maintain an injured individual in a location that doesn't readily support a Medevac?

If the capability we're trying to enhance can be improved with a joint effort—let's do it. But don't in any way compromise that capability, because it is essential to the mission of the Navy as we look to the future.

Training

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questions and measurements.

Oftentimes an individual serves as a P.I. and also as an IRB member. In that case, the learner would complete coursework for IRB members, which offers a much broader curriculum (this doesn't

apply to “extramural” performers).

Choosing the correct track and learner group will ensure personnel take the right training and avoid adding unneeded modules to the learner's completion requirement.

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